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| | 09/844,980 | 04/27/2001 | Robert D. Juncosa | ORCH 0182 PUS | 1649 | |
| | 75 | 590 01/30/2003 | | | | |
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| | 28333 Telegrap | oh Road | u. | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary Summary | | | | 1 | | | | |
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| ## Diffice Action Summary Examiner B.J. Forman B.J | | 9 | Application No. | Applicant(s) | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE of this communication. - Exclusions of time may be evaluable under the provisions of 3.7 CFR 1.136(s). In or worst, however, may a reply be timely filled on arts S1(s) (box VTHS from the miled) date of the communication. - If the peach for reply appealmed status is large time to the provisions of 3.7 CFR 1.136(s). In or worst, however, may a reply be timely filled on set S1(s) (box VTHS from the miled) date of the communication. - If the peach for reply appealmed status is large time to the provisions of 3.7 CFR 1.136(s). In or worst, however, may a reply be timely filled on set S1(s) (box VTHS from the miled) date of the communication. - If the peach for reply appealmed status is large time to the miled date of the communication to accume ADANDONED (3.8 U.S.C. 6, 13.13). - Failunce trapy white the set or cented periods for reply with. It is status to the communication are status. - Failunce trapy within the set or cented periods for reply with. It is status to the communication are status. - Failunce trapy within the set of the S7 CFR 1.136(s). - Failunce trapy within the set or cented periods for reply with. It is status. - Failunce trapy within the set of the set of the replication is a communication. - Failunce trapy within the set of the set of the replication is a communication. - Failunce trapy within the set of the S7 CFR 1.136(s). - The set of this communication is the provision of the set of the communication is a communication. - Failunce trap with the set of the set of the communication. - Status - The set of the communication is the content of the set of the communication is a content of the communication. - The set of the communication is a content of the communication. - The set of the communication is content on the set of the communication. - The communication is placed to the set of the communication. - The communication is placed to the set of the communication. - The | 055 | 055 | | JUNCOSA ET AL. | | | | |
| The MALING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of mumpy be available unser the provision of 3°C FR 1.13(6). In neveral however, may a reply be timely filled If the period for reply specified above is less than tirty (20) days, a reply within the scattatory interiors and the provision of the period for reply specified above. The maniferation statistory period with apply and will sorge X(6) (MONTS for the broadled state). If the period for reply specified above, the maniferance attacking period will apply and will sorge X(6) (MONTS for the broadled state). If the period for reply specified above, the maniferance attacking period will be considered states. If the period for reply specified above, the maniferance attacking period will be considered states. If the period for reply specified above, the maniferance attacking period of the communication. If the period for reply specified above, the maniferance and the state attacking septembers and the state attacking septembers. A reply received by the Ditto later than first moniferation and the state attacking septembers. A replication septembers are attacked at the state attacked and the state attacking septembers. Status Status Responsive to communication(s) filed on 10 October 2002. 2e) This action is FINAL. 2b) This action is non-final. 3) Since this application is condition for sillowance except for formal matters, prosecution as to the merrits is closed in accordance with the practice under Exparts Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 9-13 is/are period in the practice under Exparts Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 9-13 is/are adjected to septembers and the state and the s | Οπισε Αστιοί | Summary | Examiner | Art Unit | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SETTO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. E-bitameter of time may be availed under the provisions of 37 CFR 1.13(a), in no event, however, may a reply be timely filled of the communication. If the predict from the resulting date of this communication. If the predict from the resulting date of the communication. If the predict from the resulting date of the communication. If the predict from the resulting date of the communication. If the predict from the predict from the resulting date of the communication. Fallure is resty within the set or extended select for reply with by statute, cause the application to become ABANDONED (89 U.S.C. § 133). Any reply reserved by the Critical set then three minight is der the homeling date of this communication, even if timely filled, may reduce any any prediction and plant term adjustment. Set 37 CFR 1.704(b). Status 11 No Responsive to communication(s) filled on 10 October 2002. Status 12 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 9-13 is/are pending in the application. 4a) Claim(s) 9-13 is/are pending in the application. 4b) Claim(s) 9-13 is/are allowed. 6i) Claim(s) 9-13 is/are allowed. 6i) Claim(s) 9-13 is/are allowed. 6i) Claim(s) 9-13 is/are solicated to by the Examiner. 7) Claim(s) 18-14-28 is/are withdrawn from consideration. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filled on 18-14-28 is/are withdrawn from consideration from the Examinor. If approved, corrected drawings are required in reply to this Office action. 11) The proposed drawing correction filled on 18-14-14-14-14-14-14-14-14-14-14-14-14-14- | 71 - 1441 110 5 4 7 | | | | | | | |
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| a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | | | un priority undor 25 H.C.C. | \$ 110(a) (d) a= (f) | | | | |
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| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152) | Attachment(s) | | | | | | | |
| | 2) Notice of Draftsperson's Patent | Drawing Review (PTO-948) | 5) Notice of | | | | | |

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DETAILED ACTION

1. This action is in response to papers filed 10 October 2002 in Paper No. 9 a Terminal Disclaimer was filed and the rejections of the previous office action were discussed. The previous rejections in the Office Action of Paper No. 8 dated 19 July 2002 are withdrawn in view of the Terminal Disclaimer, Applicant's discussion and new grounds for rejection. New grounds for rejection are discussed.

The examiner for this application has changed. Please address future correspondence Examiner Forman, Art Unit: 1634.

Claims 9-13 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 9, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraus et al (U.S. Patent No. 6,198,869 B1, filed 17 May 1999).

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Regarding Claim 9, Kraus et al disclose a analysis device comprising a housing, at least one glass slide member positioned in the housing, an elastomer member positioned in the housing, said housing urging the elastomer member into a sealing arrangement with the at least one glass slide member, said elastomer member having at least one channel thereon at least one inlet port and at least one outlet port wherein materials entering the housing through the at least one inlet port are transported through said at least one channel and out through said at least one outlet port (Column 3, line 62-Column 4, line 25 and Column 7, lines 30-61).

Regarding Claim 12, Kraus et al disclose the device wherein said elastomer member provides a liquid tight seal on said glass slide member without the need for adhesives, gaskets or other sealing members between the glass slide member and the elastomer member i.e. self-adhesion (Column 4, lines 15-25 and Column 7, lines 41-43).

Regarding Claim 13, Kraus et al disclose the device wherein said elastomer member is made from a material selected from the group consisting of polydimethylsiloxane or other elastomeric material having an inherent sealing affinity (Column 4, lines 2-7).

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4. Claims 9, 12 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Novartis (WO 98/227999, published 28 M17 1998).

Regarding Claim 9, Novartis discloses a analysis device comprising a housing, at least one glass slide member positioned in the housing, an elastomer member positioned in the housing, said housing urging the elastomer member into a sealing arrangement with the at least one glass slide member, said elastomer member having at least one channel thereon at least one inlet port and at least one outlet port wherein materials entering the housing through the at least one inlet port are transported through said at least one channel and out through said at least one outlet port (page 5, first through third full paragraphs).

Regarding Claim 12, Kraus et al disclose the device wherein said elastomer member provides a liquid tight seal on said glass slide member without the need for adhesives, gaskets or other sealing members between the glass slide member and the elastomer member i.e. self-adhesion (page 5, third full paragraph).

Regarding Claim 13, Kraus et al disclose the device wherein said elastomer member is made from a material selected from the group consisting of polydimethylsiloxane or other elastomeric material having an inherent sealing affinity (page 5, first full paragraph).

5. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurimura et al (U.S. Patent No. 5,517,870, issued 21 May 1996).

Regarding Claim 9, Kurimura et al disclose a analysis device comprising a housing (flow cell unit, Fig. 3, #10), at least one glass slide member (Fig. 3, #25) positioned in the housing, an elastomer member (O-rings, Fig. 3, #28a & #28b) positioned in the housing, said housing urging the elastomer member into a sealing arrangement with the at least one glass slide member, said elastomer member having at least one channel thereon at least one inlet

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port and at least one outlet port wherein materials entering the housing through the at least one inlet port are transported through said at least one channel and out through said at least one outlet port (Column 7, lines 40-58 and Fig 3).

Regarding Claim 10, Kurimura et al disclose the device wherein a plurality of inlet ports and outlet ports are provided in said elastomer member (Column 7, lines 50-58).

Regarding Claim 11, Kurimura et al disclose the device wherein two glass slide members are provided, one positioned on each side of said elastomer member has at least one channel on each side i.e. the channel traverses the O-ring (Column 7, lines 40-50).

Regarding Claim 12, Kurimura et al disclose the device wherein said elastomer member provides a liquid tight seal on said glass slide member without the need for adhesives, gaskets or other sealing members between the glass slide member and the elastomer member (Column 8, lines 23-28).

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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7. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (U.S. Patent No. 5,928,880, filed 11 June 1997) in view of Novartis (WO 98/227999, published 28 M17 1998).

Regarding Claim 9, Wilding et al teach a analysis device comprising a housing (Column 9, lines 43-57), at least one glass slide member positioned in the housing, an elastomer member positioned in the housing, said housing urging the adhesive member into a sealing arrangement with the at least one glass slide member, said adhesive member having at least one channel thereon at least one inlet port and at least one outlet port wherein materials entering the housing through the at least one inlet port are transported through said at least one channel and out through said at least one outlet port (Column 8, lines 25-41 and Fig 4-6). Wilding et al teach the glass slide is held within the device using an adhesive member (Column 13, lines 15-25) but they do not teach the composition of the adhesive member comprises an elastomer. However, adhesive members comprising elastomer were well known in the art at the time the claimed invention was made as taught by Novartis (page 5, third full paragraph). Novartis teaches a similar device comprising a housing, at least one glass slide member positioned in the housing, an elastomer member positioned in the housing, said housing urging the elastomer member into a sealing arrangement with the at least one glass slide member, said elastomer member having at least one channel thereon at least one inlet port and at least one outlet port wherein materials entering the housing through the at least one inlet port are transported through said at least one channel and out through said at least one outlet port (page 5, first through third full paragraphs) wherein the elastomer member is the preferred because the elastomer is self-adhesive which on adhesion results in a tight seal (page 5, third full paragraph).. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the elastomer seal of Novartis to the seal of Wilding et al to thereby provide a tight seal simply by self-adhesion as taught by Novartis (page 5, third full paragraph).

Regarding Claim 10, Wilding et al teach the device wherein a plurality of inlet ports and outlet ports are provided in said elastomer member (Column 4, lines 59-62).

Regarding Claim 11, Wilding et al teach the device wherein two glass slide members are provided, one positioned on each side of said elastomer member has at least one channel on each side i.e. the channel traverses the O-ring (Column 8, lines 37-40).

Regarding Claim 12, Wilding et al teach the device wherein said adhesive member provides a liquid tight seal on said glass slide member without the need for adhesives, gaskets or other sealing members between the glass slide member and the adhesive member (Column 13, lines 15-25).

Regarding Claim 13, Wilding et al teach the device wherein the adhesive member has an inherent sealing affinity (Column 13, lines 15-25) but they are silent regarding the composition of the sealing member. However, adhesive members having inherent sealing affinity were well known in the art at the time the claimed invention was made as taught by Novartis (page 5, third full paragraph) who teach the composition of elastomers having inherent sealing affinity comprises polydimethylsiloxane (page 5, first through third full paragraphs). Additionally, Novartis teaches their elastomer member comprising polydimethylsiloxane is the preferred because the elastomer is self-adhesive which, on adhesion, results in a tight seal (page 5, third full paragraph). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polydimethylsiloxane elastomer of Novartis to the adhesion of Wilding et al to thereby provide a tight seal simply by self-adhesion as taught by Novartis (page 5, third full paragraph).

Conclusion

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

W

BJ Forman, Ph.D. Patent Examiner Art Unit: 1634 January 23, 2003